LEGISLATIVE SERVICES AGENCY
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS

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FISCAL IMPACT STATEMENT

LS 6479 **DATE PREPARED:** Feb 12, 2001
BILL NUMBER: HB 1487 **BILL AMENDED:** Feb 8, 2001

SUBJECT: Newborn Screening.

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FUNDS AFFECTED: X **GENERAL** **IMPACT:** State & Local
X **DEDICATED**
X **FEDERAL**

Summary of Legislation: (Amended) This bill expands the Newborn Screening Program, which requires infants to be examined for certain disorders, including disorders that can be detected by tandem mass spectrometry. The bill establishes procedures to determine fees for collection of specimens and testing using tandem mass spectrometry. The bill also allows the State Department of Health to develop criteria and procedures to determine if a laboratory should conduct tests using tandem mass spectrometry.

Effective Date: July 1, 2001.

Explanation of State Expenditures: (Revised) *Summary:* This bill will allow the expansion of the inborn metabolic disorders testing that the Department of Health may require every infant to undergo at the earliest feasible time. The estimated General Fund impact of an expansion in the number of metabolic disorders screened is $271,100. This includes additional costs to the Medicaid program and the state employee health plans. This dollar amount does not include costs associated with the ongoing medical treatment and nutritional therapy needed by affected individuals identified by the screening program nor does it include costs that may be avoided as a result of early identification of affected individuals.

Background: Current state law requires screening for: phenylketonuria, hypothyroidism, hemoglobinopathies, galactosemia, maple syrup urine disease, homocystinuria, and allows screening for other inborn errors of metabolism that result in mental retardation and that are designated by the State Department of Health. This bill permits the Department to expand newborn screening to include disorders that are detectible by tandem mass spectrometry. The bill also includes two additional conditions on the list of disorders required to be screened. Through its rule-making authority, the Department recently implemented screening for biotindinase deficiency and congenital adrenal hyperplasia. Some of the other additional disorders (permitted to be screened by the bill) with early diagnosis and dietary adjustments can have significantly better outcomes; others can be detected and diagnosed but do not respond consistently to treatment.[1]

The availability of new laboratory testing equipment is the impetus behind the expansion of the newborn screening program. Tandem mass spectrometry is a relatively new technology that permits rapid, sensitive, and accurate measurement of many different kinds of metabolites requiring minimal sample preparation. The computerized system has the capability to handle the large numbers of samples that are processed in universal newborn screening programs. Tandem mass spectrometry cannot currently replace all the tests used to screen for all of the currently required conditions. However, it is a more accurate and sensitive test for certain required screens (phenylketonuria, maple syrup urine disease, and homocystinuria) and permits the screening program to be expanded to include a number of disorders (approximately 30 total) that are not currently covered under the provisions of the statute. Some of these disorders are relatively common, difficult to detect before the onset of symptoms, and whose outcome is substantially improved by early treatment. The Department of Health currently has the ability to implement the use of tandem mass spectrometry. However, the bill allows the full range of screening available with this technology. The Department will still be required to define the conditions to be screened and reported through the rule-making process.

The Department of Health currently screens about 84,000 infants annually, or 99.6% of all births in the state, for eight conditions. The laboratory charge for the screening test is about $22.50. The laboratory charge is based on the cost necessary to screen all infants. Even if a repeat screen is necessary, there is no additional charge for the laboratory. This is significant since if the laboratory samples are collected too early, before sufficient metabolites are present in the infant's blood, the screens must be repeated. Repeat screens are performed on approximately 50% of the infants. It is not known at this time if the sensitivity of tandem mass spectrometry will allow for a reduction in the number of repeat screens that are currently required. The Department also adds on a $7 fee for the administrative expenses associated with the Newborn Screening Program. Hospitals may have an additional associated phlebotomy charge for the collection of the specimen.

Allowing the expansion of the Newborn Screening Program to include conditions detectable by tandem mass spectrometry would not necessarily mean that the Department would automatically start using this technology. However, should the opportunity to convert selected existing testing protocols to the more accurate test arise, the Department could screen and report for disorders detectable under its expanded capacity. Indiana University currently is the contracted laboratory for the state newborn screening exams. IU does not currently have tandem mass spectrometry equipment capable of performing the screens for all newborns in the state. The system, if acquired, could be financed on the basis of an incremental increase in the laboratory screening fees charged for newborn screening. The literature indicates that tandem mass spectrometry "probably can be added to existing newborn screening systems for an incremental cost on the order of $10 per sample".[1]

Potential Fiscal Impact: If the Department chooses to adopt the new technology and expand the Newborn Screening Program to incorporate the additional testing, the Medicaid program and the state employee health benefit program will incur additional costs. The bill specifies that the Office of Medicaid Policy and Planning must pay for the cost of collection and laboratory fees resulting from the implementation of testing using tandem mass spectrometry. This will result in an impact on the Medicaid program.

The Department currently has the ability to add the technology and increase the newborn screening fee. The Department would not necessarily be allowed to increase the number of disorders they may screen and report without changes in the statute. This scenario would result in local hospitals covering the increased cost of the test within the current level of DRG payments until the increased cost is included in a rebased hospital DRG payment and managed care contracts are renegotiated by the Medicaid program.

State-wide, the annual additional cost to all payers is estimated to be $1,260,000. (84,000 births x 1.5

rescreens x $10). Provisions included in P.L.91-1999 require the State and private insurers to cover the cost of the testing. In FY 2000, Medicaid paid for approximately 45,200 deliveries. The total annual cost to Medicaid is estimated to be $678,000. The state share of the total incremental cost would be about $257,600.

The additional testing protocol may also impact the cost of state employee health care benefits. Additional costs are estimated to be about $13,500. (900 births in CY 2000 x 1.5 x $10). Costs have been revised to reflect updated information regarding the number of births from the Medicaid Program and State Personnel.

The inclusion of additional disorders in the newborn screening menu could increase the number of patients identified with metabolic disorders each year. Many of these conditions result in significant medical complications or death if undetected. If treatable conditions are identified in a newborn screen, the medical resources necessary to provide for ongoing nutritional and medical needs will increase. However, there could be long term cost savings which will offset these expenses. The cost estimates above deal only with the cost of screening the general population; they do not include the additional expenses or cost savings associated with the identification of affected individuals.

Explanation of State Revenues:

Explanation of Local Expenditures: As with the state, an expansion in the cost associated with the Newborn Screening Program may result in increased insurance premiums for the employee benefit plans purchased by local governments and school corporations. The impact on local units of government would vary depending on the specific benefit packages provided to employees.

Explanation of Local Revenues:

State Agencies Affected: All State Agencies; Department of Health, Newborn Screening and Children with Special Healthcare Needs; Family and Social Services Administration, Medicaid Division.

Local Agencies Affected:

Information Sources: Kathy Gifford, Assistant Secretary, Office of Medicaid Policy and Planning; Ed Blume, Newborn Screening Program, State Department of Health, 233-1252 and web page located at http://www.state.in.us/isdh/dataandstats/nat_intermpreg_marr/nat_1997/natality.htm; Keith Beesley, Department of Personnel, 232-3062; Ms. Jackie Bradford, Program Advocate, 684-3557.

[1] "Tandem Smass Sectrometry in Newborn Screening" American College of Medical Genetics / American Society of Human Genetics Test and Technology Transfer Committee Working Group, Genetics in Medicine, July/August 2000, Vol. 2, No. 4; "Newborn Screening," Rhonda Gonzalez, NCSL Legisbrief, National Conference of State Legislatures, June/July 2000, Vol. 8, No. 27.